IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DEY LP and DEY, INC.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civil Action No. 08-372-JJF
	:	
SEPRACOR INC.,	:	
	:	
Defendant.	:	

MEMORANDUM ORDER

Pending before the Court is Sepracor's Motion For Certification Pursuant to 28 U.S.C. § 1292(b) And To Stay Proceedings Pending Resolution Of Appeal. (D.I. 22.) For the reasons discussed, Sepracor's Motions will be denied.

On June 20, 2008 Plaintiffs Dey L.P. and Dey, Inc. (collectively, "Dey") brought this action, seeking a declaratory judgment that their proposed generic levalbuterol hydrochloride inhalation products, if marketed, would not infringe U.S. Patent No. 6,341,289 ("the '289 patent"), which is owned by Defendant Sepracor. (D.I. 1.) On August 13, 2008, Sepracor moved to dismiss for lack of subject matter jurisdiction, alleging that there is no justiciable controversy regarding infringement or validity of the '289 patent. (D.I. 8; D.I. 9.) In light of the Federal Circuit's decisions in Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd., 527 F.3d 1278 (Fed. Cir. 2008) and Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353 (Fed. Cir. 2008), the Court denied Sepracor's Motion on January 30, 2009. (D.I. 19.) In its Memorandum Opinion denying Sepracor's Motion

To Dismiss (D.I. 19), the Court set forth in detail the relevant statutory scheme and litigation history. The reader is referred to this Memorandum Opinion (D.I. 19) for the background pertinent to the Instant Motion.

The thrust of Sepracor's Motion For Certification is that there remains a "substantial ground for difference of opinion" as to whether Dey's covenant not to sue eliminated subject matter jurisdiction over the instant dispute. (See D.I. 24 at 8.) Sepracor maintains that this is demonstrated by (1) the presence of a dissenting opinion and a divided panel in the Federal Circuit's Caraco opinion, (2) divergent outcomes in Caraco and Janssen that may reflect underlying differences of opinion among Federal Circuit Judges, (3) the fact that this Court stated the instant case was "intermediate" to Caraco and Janssen, and (4) the existence of academic commentary critical of the Caraco opinion.[1] (D.I. 24 at 8-10.)

[1] Throughout briefing of both the Motion to Dismiss (D.I. 8) and the instant Motion, Dey also relied heavily on two decisions from the District of New Jersey that reached a conclusion contrary to the Federal Circuit's Caraco decision. See Ivax Pharms., Inc. v. Astrazeneca AB, 2008 U.S. Dist. LEXIS 66177 (D.N.J. Aug. 28, 2008); Dr. Reddy's Labs., Ltd. v. AstraZeneca AB, 2008 U.S. Dist. LEXIS 66176 (D.N.J. Aug. 28, 2008). However, as Dey notes, the District of New Jersey has since reversed its decision in these cases. (See D.I. 29, Exh. 4 at 5:20-7:24.) These cases do not support Sepracor's position on this dispute.

The fact that Caraco included a dissent and fomented academic criticism is plainly insufficient to warrant an interlocutory appeal. Indeed, as Dey notes, to conclude that this justifies an interlocutory appeal would give dissenting opinions and academic commentary far too much legal stature.

The other considerations Sepracor identifies, however, pertain more directly to whether Caraco and Janssen supply adequate guidance as to how the Hatch-Waxman statutory scheme should be applied in this instance and raise the additional concern that Caraco and Janssen are in tension. In its Reply Brief, Sepracor explains in greater detail its position on these issues. As to Caraco, Sepracor explains that granting declaratory judgment jurisdiction in Caraco allowed the declaratory judgment plaintiff to potentially market its generic at an earlier date, yet at the same time preserved the first Paragraph IV ANDA filer's 180-day exclusivity period. (See D.I. 30 at 4-5.) In Janssen, by contrast, had declaratory judgment jurisdiction been granted, the declaratory judgment plaintiff could not have gone to market any earlier than otherwise possible, but the first Paragraph IV ANDA filer's 180-day exclusivity period would have been destroyed. (See id.) Here, as Sepracor notes, we have yet a third scenario: granting declaratory judgment jurisdiction will not only allow Dey to possibly go to market earlier, but will also destroy Breath's

180-day exclusivity period. In these circumstances, Sepracor contends that the Federal Circuit should be consulted for further guidance as to how Caraco and Janssen may be harmonized. Likewise, Sepracor contends that the Federal Circuit should weigh in on whether the policy goals underlying the 180-day exclusivity period (i.e., incentivizing early patent challenges) give way to the policy goal of enabling generics to come to market earlier, such that the Court should decline declaratory judgment jurisdiction in this case.

The Court does not agree that additional guidance on these issues is necessary. Though Sepracor contends that Caraco and Janssen are somehow inconsistent, there can be no doubt that significant differences in the facts explain the different results in these two cases and that they are thus reconcilable. Indeed, in Janssen the outcome hinged upon the declaratory judgment plaintiff's stipulation to the validity and infringement of one Orange Book patent. See Janssen, 540 F.3d at 1360 ("We agree with the parties that if Apotex had not stipulated to the validity of the '663 patent, then Caraco would have been controlling."). Because of this stipulation, the only non-speculative "harm" the declaratory judgment plaintiff could have avoided through its declaratory judgment actions was the need to wait 180 days for the first Paragraph IV filer to enjoy its exclusivity period before going to market. (See D.I. 19 at 17-

18.) As the Federal Circuit explained, this "harm" alone does not support declaratory judgment jurisdiction. See Janssen, 540 F.3d at 1361-62.

Here, however, Dey has done nothing similar to the stipulation in Janssen so as to voluntarily delay its market entry until Breath first begins enjoying its 180-day exclusivity period. Accordingly, to the extent the Federal Circuit in Janssen expressed concern over preserving a first Paragraph IV ANDA filer's 180-day exclusivity period, this concern carries far less weight in the instant case.

On the other hand, by virtue of the settlement agreement between Breath and Sepracor, Breath can go to market - and hence begin enjoying its exclusivity period - no earlier than August 2012. Permitting Breath to in the meantime block all other generics from entering the market is precisely the situation that the relevant 2003 amendments to the Hatch-Waxman Act were designed to prevent.[2] Put another way, allowing Breath to

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[2] See, e.g., 149 Cong. Rec. S16105 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch) ("Nevertheless, I am pleased that the Senate language that allowed long-term parking of exclusivity was modified in an important way by the conferees."); Legislative and Regulatory Response to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace, 108th Cong. 13 (2003)(statement of Daniel E. Troy, Chief Counsel, Food and Drug Administration) ("That said, we are working, we think, very productively with the staff on S. 1225 to embody more a, shall we say, us it or lose to approach so that someone can't park their exclusivity."); 149 Cong. Rec. S15885 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) ("[W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company

initiate a challenge to a pharmaceutical patent, give up that challenge, and then pocket the 180-day exclusivity period for an extended period - to the detriment of all other generic manufacturers - does not, in the Court's view, vindicate the policy goal underlying the 180-day exclusivity period. Accordingly, although allowing declaratory judgment jurisdiction may cause Breath to lose its 180-day exclusivity period, the Court nevertheless concludes that the instant declaratory judgment action should go forward.

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Sepracor's Motion For Certification Pursuant to 28 U.S.C. § 1292(b) And To Stay Proceedings Pending Resolution Of Appeal (D.I. 24) is **DENIED**.

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could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the 'failure to market' provision and force the first generic to market. In each of these and in other circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period.").

2. Within twenty (20) days of the date of this Order the parties shall submit a joint, proposed Revised Scheduling Order for the Court's consideration. If the parties are unable to reach agreement, they shall outline their disputes in the joint, proposed Scheduling order.

April 16, 2009
DATE

UNITED STATES DISTRICT JUDGE